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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,264	01/20/2006	Martin F. Bachmann	1700.0660000/BJD/WBC	5243

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EXAMINER	
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ART UNIT	PAPER NUMBER
1645	

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01/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/565,264	BACHMANN ET AL.	
	Examiner	Art Unit	
	Oluwatosin Ogunbiyi	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,17 and 23-26* is/are pending in the application.

4a) Of the above claim(s) *14,15,17 and 26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and 23-25* is/are rejected.

7)☒ Claim(s) *6* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 January 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment to the claims filed 1/20/06 has been entered into the record. Claims 1-15, 17, 23-26 are pending in the application. Claims 16 and 18-22 have been cancelled. Claims 1-13 and 23-25 are under examination

Priority

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Drawings

The drawings in this application have been accepted. No further action by Applicant is required.

Information Disclosure Statement

An information disclosure statement has not been filed.

Election/Restrictions

Applicant's election of Group I claims 1-14 and 23-25 and the species of synthetic oligonucleotide and cationic stealth liposome without traverse of the restriction requirement filed 10/18/2007 is acknowledged.

Claims 14, 15,17 and 26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5,8,9,10, 11, 12 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14,23,24, 27, 30,31, 35 of copending Application No.11/638664 ('664). Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following:

The '664 application claims are drawn to a composition comprising a liposome (see claim 1 and 14 of '664) and an A- type CpG (see claim 23 of '664) wherein in all the nucleotides of the A-type CpG oligonucleotide are phosphodiester nucleotides (see claim 35 of '664) and further wherein said A-type CpG is packaged (bound) to said liposome (see claim 1 of '664). Claim 27 of '664 teaches the A-type CpG palindromic

sequence of claim 9 of the instant application. Claim 30 of '664 teaches the A-type CpG containing sequence of claim 11 (compare SEQ ID No's 32, 33, 25, 26 and 27 of '664 with SEQ ID No's 9,10,11,12 and 3 of the instant application respectively). The sequences of the '664 application meets the limitations of claims 2-5 of the instant claims in that the sequences comprise poly G motifs at the 5' and 3' ends, the G nucleotides are phosphodiester (see claim 35 of '664) and meet the structural motifs of instant claims 4 and 5. The '664 sequences set forth above comprise the palindromic sequence of instant claim 9 and are flanked at the 5' by at least 3 and at most 10 guanosine and flanked at 3' end by at least 6 and at most 10 guanosine entities (see Seq ID NO:25 of '664, for example).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Objections

Claim 6 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 6 recites the limitation "5'R1R2CGTR3Y1CGY2Y3'" Claim 5 from which claim 6 depends recites the structures "5'R1Y1CGR2Y23' or R1Y1CGY2R23'" and does not recite the structure of claim 6 as set forth above. The structure of claim 6 does not further limit the structures found in claim 5. It appears the structure of claim 6 was originally present in claim 5 but has now been cancelled. Applicants are respectfully requested to correct or clarify the dependency of claim 6.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites the limitations "R3 and Y3". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102 and 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, 8, 9, 10, 11 (SEQ ID NO: 7), and 23-25 are rejected under 35 U.S.C. 102(b) as anticipated by Hartmann et al WO 01/22990 A2 published April 5 2001.

The claims are drawn to a composition for enhancing the production of IFN alpha in an animal comprising: (a) liposome; (b) at least one A-type CpG; wherein all the nucleotides of the A-type CpG oligonucleotide are phosphodiester nucleotides and further wherein said A-type CpG is bound to said liposome.

Hartmann teaches a composition comprising a liposome (p. 38 line 15-19) and at least one A-type CpG (p. 7-8) wherein all nucleotides of the A-type CpG oligonucleotides are phosphodiester nucleotides (p. 28 line 12). Said A-type CpG comprises poly G motifs at 5' and 3' ends (p. 7-8) and the G nucleotides of the poly G motifs can be phosphodiester nucleotides (p. 28 line 12). Said A-type CpG comprises the sequence 5'R1Y1-CG-R2Y2 3' wherein R1R2Y1Y2 are any nucleotide (see SEQ ID NO: 7 on p. 7) or comprise the sequence 5'R1Y1CGR2Y2 3' or 5'R1Y1CGY2 R2 3' wherein R1 or R2 is A or G and Y1 or Y2 is C or T (see central motif present in SEQ ID

NO: 7 on p. 7) and the A-Type CpG also comprises the sequence 5'R1R2CGR3Y1CGY2Y3 3' where R1 or R2 or R3 is A or G and Y1 or Y2 or Y3 is C or T (see SEQ ID NO: 7 on p. 7). The A-type CpG of Hartmann et al is synthetic (p. 27 line 13) and comprises a palindromic sequence of GACGATCGTC (see SEQ ID NO: 7 on p. 7) wherein said palindromic sequence is flanked at its 5' terminus by at least 3 (4) guanosine entities and flanked at the 3' terminus by at least 6 guanosine entities (see SEQ ID NO: 7 on p. 7). Said A-type CpG comprises SEQ ID NO:7 of the instant application (see SEQ ID NO: 7 on p. 7) and can comprise 20 to 40 nucleotides or 20-100 nucleotides or 20-300 nucleotides (see p. 7 lines 1-3, 8-100 nucleotides). Hartmann teaches said A-type CpG greater than 8 nucleotides in length are capable of inducing an immune response if sufficient immunostimulatory motifs are present (p. 20 lines 19-23).

Note that the recitation of the use of the instantly claimed product i.e. "enhancing the production of IFNalpha" is an intended use of the claimed product and bears no patentable weight to the products as the recited use of the claimed product does not result in a structural difference between the claimed product and that of Hartmann et al as set forth supra. The prior art structure is capable of performing the intended use of the instant claims (see abstract of Hartmann et al).

Claim 11 (SEQ ID NO: 3,5,6,8-12) and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hartmann et al WO 01/22990 A2 published April 5 2001 as applied to claims 1,8,9 and 10 and 11 further in view of Lipford et al Immunology 2000, 101:46-52.

The claims are drawn to a composition for enhancing the production of IFN alpha in an animal comprising: (a) liposome; (b) at least one A-type CpG (SEQ ID NO: 3,5,6,8-12); wherein all the nucleotides of the A-type CpG oligonucleotide are phosphodiester nucleotides and further wherein said A-type CpG is bound to said liposome.

Hartmann et al is set forth supra. Hartmann does not teach A type CpG having nucleic acid sequence selected from SEQ ID NO: 3, 5, 6 or 8-12.

Lipford et al teaches that poly-guanosine (poly-G) extensions at the end (at 5' and 3' ends) of a core CpG Motif results in the stimulation of a T cell response (p. 50 right column first and second full paragraphs). Lipford also teaches that at least 4 but not less than 4 consecutive G bases are conditional for costimulation of a T cell response (p. 51 left column first full paragraph).

It would have been prima facie obvious to one of ordinary skill in the art at the time the instant invention was made to try different lengths of poly G extensions to the sequence of Hartmann et al comprising the palindromic sequence GACGATCGTC (see SEQ ID NO: 7 of Hartmann et al) as taught by Lipford et al to arrive at the instant SEQ ID NO: 3,5,6 or 8-12 with a reasonable expectation of success because it is known in the art that poly G extensions at the 5' and 3' end result in costimulation of a T cell response (Lipford et al) and Lipford teaches that at least 4 but not less than 4 consecutive G bases are conditional for costimulation of a T cell response. SEQ ID NO: 3, 5, 6 or 8-12 are obvious over the teachings of Hartmann and the teachings of Lipford as combined.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hartmann et al WO 01/22990 A2 published April 5 2001 as applied to claims 1as set forth above further in view of Gursel et al The Journal of Immunology, 2001, 167:3324-3328.

The claims are drawn to a composition for enhancing the production of IFN alpha in an animal comprising: (a) liposome; (b) at least one A-type CpG wherein all the nucleotides of the A-type CpG oligonucleotide are phosphodiester nucleotides and further wherein said A-type CpG is bound to said liposome wherein said liposome is a cationic stealth liposome.

Hartmann et al is set forth supra. Hartmann et al does not teach a cationic stealth liposome.

Gursel et al teach cationic stealth liposomes which improve the uptake and immunostimulatory activity of CpG oligonucleotides (see abstract p. 3324, p. 3324 left column third full paragraph) and fig. 1 p. 3325.

It would have been prima facie obvious to one of ordinary skill in the art at the time the instant invention was made to use a cationic stealth liposome in the composition of Hartmann et al as taught by Gursel et al resulting in the instant invention with a reasonable expectation of success. The motivation to do so is provided by Gursel et al who teaches that cationic stealth liposomes improve the uptake and immunostimulatory activity of CpG oligonucleotides in vitro and in vivo and that the immunotherapeutic potential of CpG ODN is enhanced.

Status of the Claims

Claims 1-13 and 23-25 are rejected.

Claims 6 is objected to.

No claims are allowed.

Claims 14,15,17 and 26 are withdrawn as being drawn to non-elected invention or specie.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Oluwatosin Ogunbiyi whose telephone number is 571-

272-0855. The examiner can normally be reached on M-F 8:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisory Examiner Shanon Foley can be reached on 571-272-0898.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Oluwatosin Ogunbiyi
Examiner
Art Unit 1645

SHANON FOLEY
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